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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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THE SCRIPPS RESEARCH INSTITUTE
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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/788,992

Applicant(s)

GILULA ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-18 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) 11-18 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-10 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group I, claims 1, 5-10, and 24 on 11/20/06 is acknowledged. The selected species are SEQ ID NO: 5 and SEQ ID NO: 42.

Claims 1, 5-10, and 24 are being considered on the merits.

Claims 11-18 and 21-23 are withdrawn from consideration as directed to a non-elected invention.

The amendment presented fails to comply with the **Revised Amendment Format 37 CFR 1.121**. Claim 1 is not amended yet “cis” is underlined partially.. In addition, claim 24 is designated as “new”. This is an original claim. Correction is **required**.

Copies of the cited references are requested to complete the record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-10, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the recitation “An isolated and purified mammalian fatty-acid amide hydrolase (FAAH) Isolated fatty-acid amide ...” Correction is required.

The claim 5 encompasses an improper Markush grouping because it does not use the form “selected from the group consisting of A, B, AND C). It uses “a group” which renders the claim indefinite as to what is intended. See MPEP 2173.05(h)(a). In addition, the phrase “is

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characterized by inclusion of an amino acid sequence” is confusing. Amendment to --wherein the FAAH has an amino acid...--.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-6 and 8-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Maurelli *et al.*.

The claims are drawn to a fatty acid amide hydrolase (FAAH) which is capable of hydrolyzing a variety of amides..

The cited reference discloses an FAAH which appears to be identical to the presently claimed enzyme (see, e.g., page 84 and Table 1, page 85), since it is capable of hydrolyzing at least anandamide and cis-9,20-octadecenoamide. The referenced enzyme appears to be identical to the presently claimed FAAH and is considered to anticipate the claimed enzyme since it is taught to be effective to hydrolyze substantially similar amide substrates and is similarly isolated from mammals such as mice.. Consequently, the claimed FAAH appears to be anticipated by the reference, even though the respective sequence information is not provided. It is noted that the mouse enzyme appears to comprise SEQ ID NO: 5.

In the alternative, even if the claimed FAAH is not identical to the referenced enzyme with regard to some unidentified characteristics, the differences between that which is disclosed

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and that which is claimed are considered to be so slight that the referenced enzyme is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed FAAH would have been obvious to those skilled in the art within the meaning of USC 103.

Furthermore, the composition is claimed as a product-by-process in claims 8-10. The reference teaches purification by isoelectrofocusing at page 86, col. 1. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Claims 1, 5-6 and 7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Deutsch *et al.*.

The claims are drawn to a fatty acid amide hydrolase (FAAH) which is capable of hydrolyzing a variety of amides..

The cited reference discloses an FAAH which appears to be identical to the presently claimed enzyme (see, e.g., page 792, Results), since it is capable of hydrolyzing at least anandamide (N-arachidonoyl ethanolamide)

The referenced enzyme appears to be identical to the presently claimed FAAH and is considered to anticipate the claimed enzyme since it is taught to be effective to hydrolyze substantially similar amide substrates and is similarly obtained from mammals such as humans. Consequently, the claimed FAAH appears to be anticipated by the reference, even though the respective sequence information is not provided. It is noted that the human enzyme appears to comprise SEQ ID NO: 5 and SEQ ID NO: 42

In the alternative, even if the claimed FAAH is not identical to the referenced enzyme with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced enzyme is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed FAAH would have been obvious to those skilled in the art within the meaning of USC 103.

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Furthermore, the composition is claimed as a product-by-process in claims 8-10. The reference teaches the native enzyme. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cravatt *et al.*.

The claims are drawn to a fatty acid amide hydrolase (FAAH) which is capable of hydrolyzing a variety of amides..

The cited reference discloses an FAAH from isolated rat brain membrane fractions which appears to be identical to the presently claimed enzyme (see, e.g., page 1508, Fig 4) since it is capable of hydrolyzing at least cis-9,20-octadecenoamide. The referenced enzyme appears to be identical to the presently claimed FAAH and is considered to anticipate the claimed enzyme since it is taught to be effective to hydrolyze substantially similar amide substrates and is similarly isolated from mammals. Consequently, the claimed FAAH appears to be anticipated by the reference, even though the respective sequence information is not provided.

In the alternative, even if the claimed FAAH is not identical to the referenced enzyme with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced enzyme is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed FAAH would have been obvious to those skilled in the art within the meaning of USC 103.

Claims 1 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ohkawa *et al.*.

The claims are drawn to a fatty acid amide hydrolase (FAAH) which is capable of hydrolyzing a variety of amides..

The cited reference discloses an FAAH which appears to be identical to the presently claimed enzyme (see, e.g., Fig. 2, page 8), since it is capable of hydrolyzing at least cis-9,20-

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octadecenoamide. The referenced enzyme appears to be identical to the presently claimed FAAH and is considered to anticipate the claimed enzyme since it is taught to be effective to hydrolyze a substantially similar amide substrate. Consequently, the claimed FAAH appears to be anticipated by the reference, even though the respective sequence information is not provided.

In the alternative, even if the claimed FAAH is not identical to the referenced enzyme with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced enzyme is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed FAAH would have been obvious to those skilled in the art within the meaning of USC 103.

Claims 1, 6 and 8-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ueda *et al.* (1995).

The claims are drawn to a fatty acid amide hydrolase (FAAH) which is capable of hydrolyzing a variety of amides..

The cited reference discloses an FAAH which appears to be identical to the presently claimed enzyme (see, e.g., page 23824), since it is capable of hydrolyzing at least anandamide (See, e.g. page 23825). The referenced enzyme appears to be identical to the presently claimed FAAH and is considered to anticipate the claimed enzyme since it is taught to be effective to hydrolyze substantially similar amide substrates and is similarly isolated from mammals. Consequently, the claimed FAAH appears to be anticipated by the reference, even though the respective sequence information is not provided.

In the alternative, even if the claimed FAAH is not identical to the referenced enzyme with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced enzyme is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Furthermore, the composition is claimed as a product-by-process in claims 8-10. The reference teaches purification by chromatography at page 23824. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before

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it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear and convincing evidence to the contrary.

Claims 1, 6, 8-10, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maurelli taken with Ueda *et al.*, Cravatt *et al.* and further taken with Koutek *et al.*, Scopes and Mayaux *et al.*

Ueda *et al.* (1995) disclose a mammalian FAAH which appears to be identical to the presently claimed enzyme (see, e.g., page 23824), since it is capable of hydrolyzing at least anandamide (See, e.g. page 23825). Maurelli discloses a mammalian FAAH which appears to be identical to the presently claimed enzyme (see, e.g., page 84 and Table 1, page 85), since it is capable of hydrolyzing at least anandamide and cis-9,20-octadecenoamide. In addition Cravatt *et al.* disclose FAAH activity in isolated rat brain membrane fractions that hydrolyzes cis-9,20-octadecenoamide (See, e.g., page 1508, fig. 4), while Koutek *et al.* teach this activity FAAH in anandamide hydrolysis. (See, e.g., page 22938).

The methods of purification used in the references may differ from the claim designated processes. However, Scopes adequately demonstrates that the purification of enzymes was routine in the art at the time the claimed invention was made by a variety of techniques (See, e.g., pages 100-114). Furthermore, Mayaux *et al.* adequately demonstrate the purification of related amidases by conventional means (See, e.g., page 6765-6766). This amidase hydrolyzes a fatty acid primary amide, i.e., aryl propionamide.

Regarding the use of trifluoroketones in the purification process, Koutek *et al.* adequately demonstrate that these compounds are known in the art to be anandamide analogs and to be useful as inhibitors at least of FAAH in anandamide hydrolysis. Since inhibition is reversible and concentration dependent, one of ordinary skill in the art would have had a reasonable expectation of success regarding the purification of the FAAH by using these compounds in an affinity chromatography purification process.

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Furthermore, the composition of claims 8-10 is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the processes of isolation and/or purification taught by Maurelli taken with Ueda *et al.*, Cravatt *et al.* by using the techniques of Koutek *et al.*, Scopes and Mayaux *et al.* for the benefits of maximizing the activity of the enzyme by its purification and, alternatively, using the cloning techniques of Mayaux *et al.* to produce the FAAH by genetic engineering means for the benefits of obtaining large amounts of the FAAH enzyme without costly isolation procedures.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651